Bayer

Bayer Corporation
Corporate Compliance
100 Bayer Road
Building 14
Pittsburgh, PA 15205-9741

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December 21, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 00N-1543, Draft Guidance for Industry: 21 CFR Part 11; Electronic Records; Electronic Signatures Glossary of Terms

Bayer Corporation appreciates the opportunity to provide comments on the Draft Guidance for Industry: 21 CFR Part 11; Electronic Records; Electronic Signatures Glossary of Terms. As a manufacturer of pharmaceuticals, biologicals, medical devices, animal health products, and consumer care products, 21 CFR Part 11 Electronic Records and Electronic Signatures has a significant impact on the Bayer Corporation organization. The comments included as an attachment to this letter represent the current thinking of subject matter experts within Bayer Corporation.

In general, we felt that a separate guidance document was not necessary for definitions. Applicable definitions should be included within each guidance document. The majority of definitions provided do not appear to expand upon the definitions already provided within the 21 CFR Part 11 regulation and do not contribute to the state of knowledge of Part 11 compliance. Guidance is needed on how to identify systems or system components that fall under the umbrella of Part 11 requirements and how to comply with Part 11 requirements.

While perhaps beyond the immediate scope of this guidance document under review, it is critical for the industry to obtain a single standard for electronic signatures. For example, the EU, as well as several states (e.g., Massachusetts) have adopted or are currently considering implementation of requirements for electronic signatures. FDA regulations should preempt the field and thereby provide protection from disparate requirements for electronic signatures.

If you have any questions regarding our comments, please contact me.

Sincerely,

Elizabeth Gaipa

Elizabeth Gaipa
Corporate Compliance Manager
Tel: 412-777-2665
Fax: 412-778-6566

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Attachment: Bayer Corporation Comments Guidance for Industry: 21 CFR Part 11; Electronic Records; Electronic Signatures Glossary of Terms

Bayer Corporation Comments
Guidance for Industry: 21 CFR Part 11; Electronic Records; Electronic Signatures Glossary of Terms
Draft Guidance – August 2001
Docket No. 00N-1543

Page Number of PDF Guidance Document	Section Title/Description	Comment/Recommendation for Revision
Page 1	1. Purpose	Recommend that an explanation of the differences between the August 1995 FDA Glossary of Computer System and Software Development Terminology and the glossary in the Draft Guidance be provided.
Pages 3-5	3. Definitions	Recommend removing all definitions that are the same as those stated in 21 CFR Part 11. No additional value is created in restating the definitions.
Page 4	3. Definitions	The definition provided for Computer Systems Validation does not define validation. Recommend using an existing accepted definition for the term.
Page 4	3. Definitions	Recommend that a definition of "computer system" be included. We recommend the following definition, "A complete functional unit composed of hardware, software, input devices, output devices, users, and procedures. The functional unit shall be able to receive input (data), conduct processing of input, and produce output (results).
Page 4	3. Definitions	Recommend that a definition for "metadata" be included. We recommend the following definition. "Data describing context, content, and structure of records and their management through time." (ISO/DIS 15489 Section 3.12)
Page 5	3. Definitions Predicate Rule	Recommend that the definition include a statement indicating that information contained within guidance documents cannot serve as Predicate Rules. While this principle may be understood, clarification would be beneficial.
Page 5	3. Definitions	Recommend removing the definition for Regression Analysis and Testing since the following definition is for Regression Testing.
Page 5	3. Definitions	Recommend that a definition be provided for revalidation.